Testing Algorithm for Laboratories Using BioFire Diagnostics Ebola Assay

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Introduction

The 2014 Ebola Zaire epidemic is the largest the world has ever seen and has crossed US borders causing widespread concern and declaration of a Public Health Emergency. The laboratory community has been actively engaged in responding to testing and biosafety concerns. Until last week, the assays that have received Emergency Use Authorization (EUA) from the US Food and Drug Administration (FDA) were available only at select state or local public health Laboratory Response Network (LRN) Reference Laboratories and the Centers for Disease Control and Prevention (CDC). On October 25 2014 the BioFire Diagnostics FilmArray Biothreat-E Panel with an Ebola virus test was given an FDA Emergency Use Authorization (EUA). Clinical laboratories that are considering implementation of this assay must remember the importance of connecting with Public Health authorities whenever Ebola Virus Disease is suspected and consider the risk/benefit of implementing this assay in their laboratory.

Considerations for Implementing Ebola Testing In Your Laboratory

- TheBioFire FilmArray Biothreat-E Panel is available as an FDA approved assay with EUA. EUA is not a full FDA approval, rather this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for detection of Ebola Zaire virus under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
- In order to report patient results to clinicians and use results for patient management in compliance with CMS CLIA regulation, laboratories are required to establish performance characteristics for the assay (e.g. complete a validation). Completion of an assay validation requires access to positive Ebola specimens which are not readily available.
- Prior to implementing any assay, laboratories should conduct a Biosafety Risk Assessment to identify sources of risk and implement safety measures to mitigate them.

Additional Resources

Patient Evaluation

- Decision Algorithm to Assist with Identifying Testing and Monitoring of Patients with Suspected Ebola Virus Disease (EVD)
  http://www.floridahealth.gov/diseases-and-conditions/ebola/index.html

Packaging and Shipping

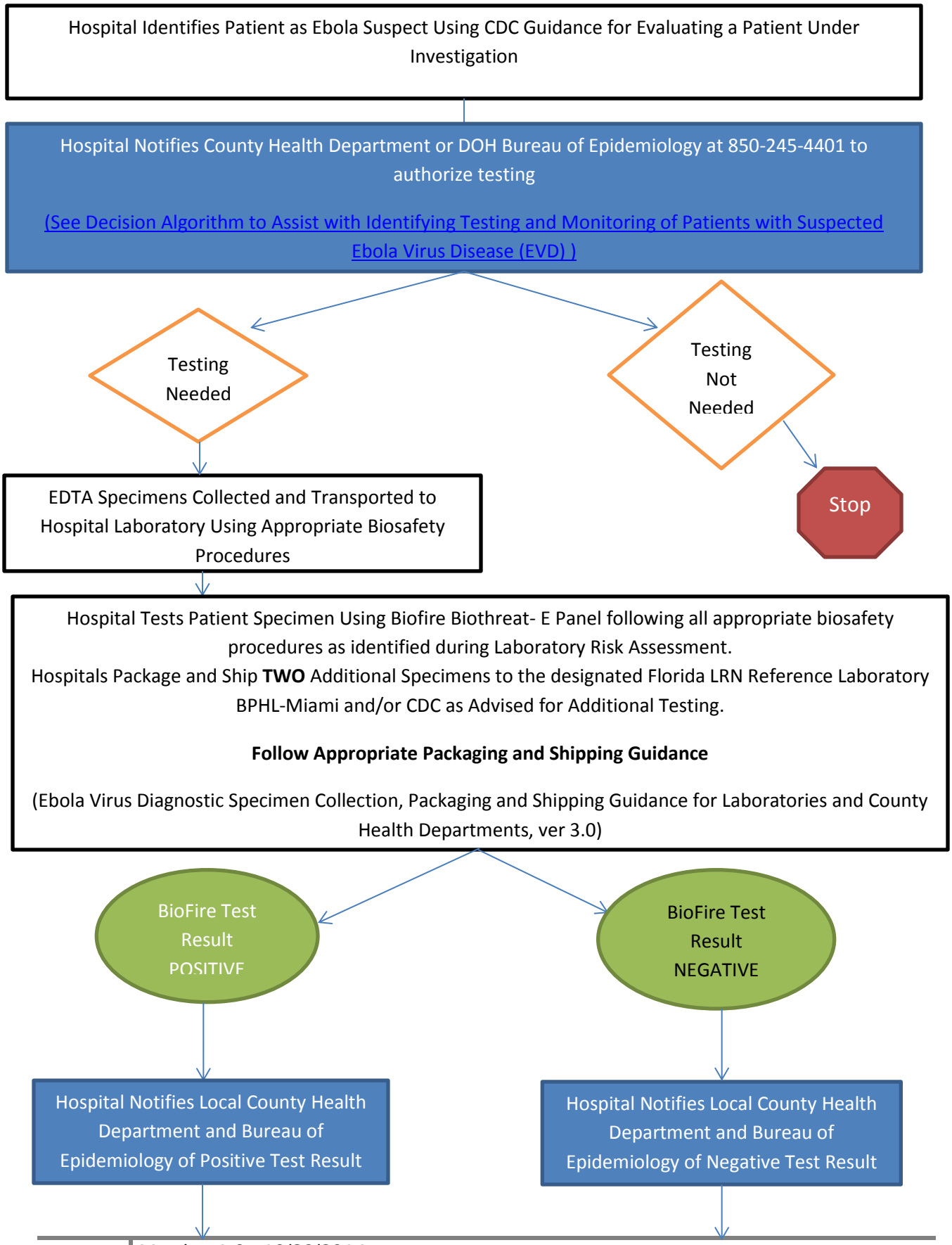
- Interim Guidance for Specimen Collection, Transport, Testing and Submission
- http://www.floridahealth.gov/diseases-and-conditions/ebola/index.html
  http://www.cdc.gov/vhf/ebola/pdf/ebola-lab-guidance.pdf
- Packaging and Shipping eLearning Course
  http://www.cdc.gov/labtraining/course_listing/packing_shipping.html

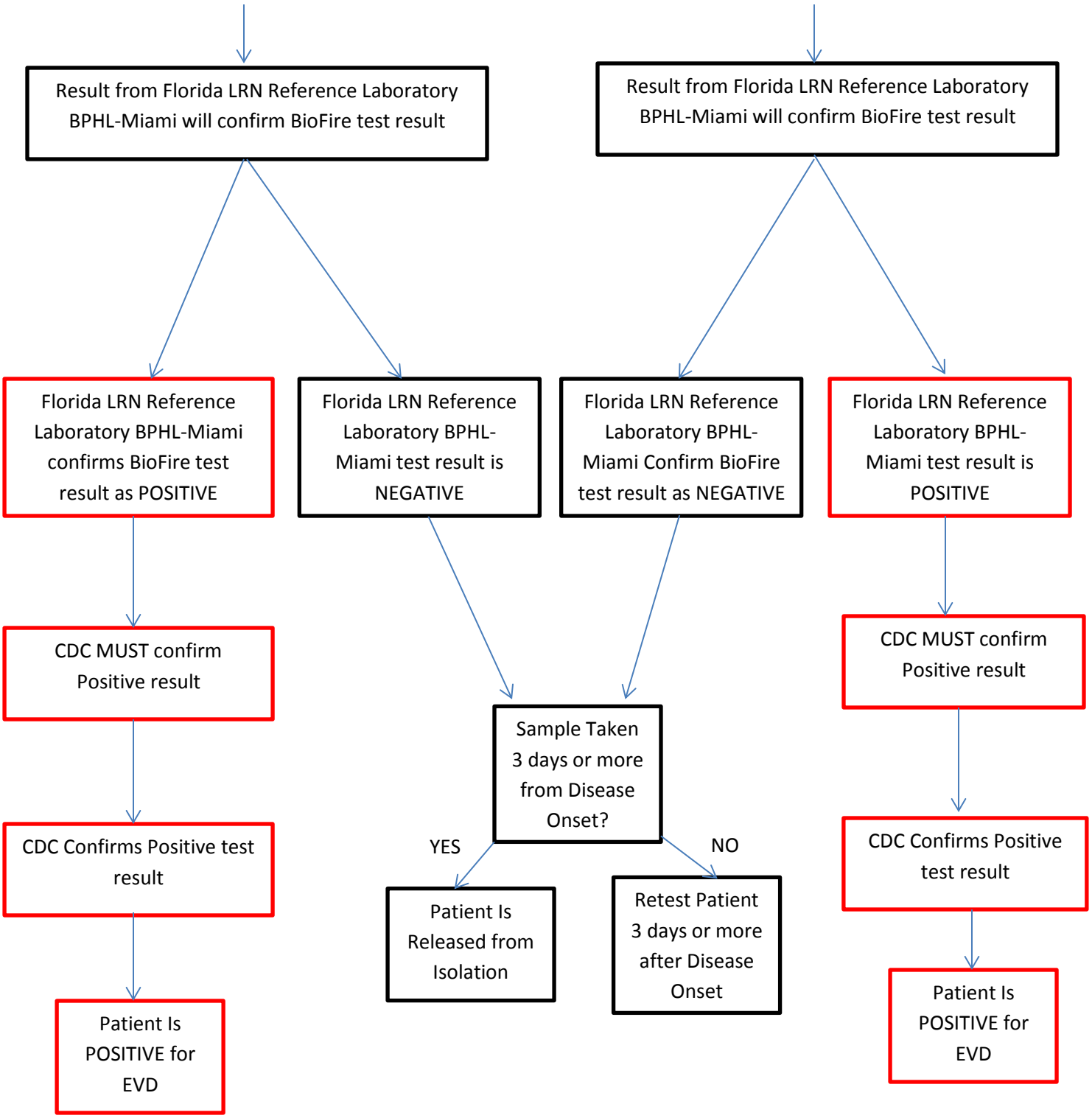
Personal Protective Equipment (PPE)

Guidance on PPE

http://www.floridahealth.gov/diseases-and-conditions/ebola/index.html

http://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html


Hospital Identifies Patient as Ebola Suspect Using CDC Guidance for Evaluating a Patient Under Investigation
Hospital Notifies County Health Department or DOH Bureau of Epidemiology at 850-245-4401 to authorize testing
(See Decision Algorithm to Assist with Identifying Testing and Monitoring of Patients with Suspected Ebola Virus Disease (EVD))
Testing Needed
Testing Not Needed
Stop
EDTA Specimens Collected and Transported to Hospital Laboratory Using Appropriate Biosafety Procedures
Hospital Tests Patient Specimen Using Biofire Biothreat- E Panel following all appropriate biosafety procedures as identified during Laboratory Risk Assessment.
Hospitals Package and Ship TWO Additional Specimens to the designated Florida LRN Reference Laboratory BPHL-Miami and/or CDC as Advised for Additional Testing.
Follow Appropriate Packaging and Shipping Guidance
(Ebola Virus Diagnostic Specimen Collection, Packaging and Shipping Guidance for Laboratories and County Health Departments, ver 3.0)
BioFire Test Result POSITIVE
BioFire Test Result NEGATIVE
Hospital Notifies Local County Health Department and Bureau of Epidemiology of Positive Test Result
Hospital Notifies Local County Health Department and Bureau of Epidemiology of Negative Test Result


Result from Florida LRN Reference Laboratory BPHL-Miami will confirm BioFire test result
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Florida LRN Reference Laboratory BPHL-Miami confirms BioFire test result as POSITIVE
Florida LRN Reference Laboratory BPHL-Miami test result is NEGATIVE
Florida LRN Reference Laboratory BPHL-Miami Confirm BioFire test result as NEGATIVE
Florida LRN Reference Laboratory BPHL-Miami test result is POSITIVE
CDC MUST confirm Positive result
CDC MUST confirm Positive result
Sample Taken 3 days or more from Disease Onset?
YES
NO
CDC Confirms Positive test result
CDC Confirms Positive test result
Patient Is Released from Isolation
Retest Patient 3 days or more after Disease Onset
Patient Is POSITIVE for EVD
Patient Is POSITIVE for EVD